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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,316	09/30/2003	Alvin Algee	A03P1065	6514
36802	7590	06/24/2005	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			GREENE, DANA D	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary

Application No.

10/676,316

Applicant(s)

ALGEE, ALVIN

Examiner

Dana D. Greene

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 18 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Examiner has given full consideration to the Applicant's remarks of 03/18/05. Unfortunately, such remarks are not persuasive and do not overcome the prior art rejections made in the office action of 02/25/05. Therefore, claims 1-3 and 7-11 remain rejected under 35 U.S.C. §102(b) as being anticipated by Helland et al. (US 5,628,774, hereinafter "Helland") and claims 4-6 and 12-15 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Helland in view of Carson (US 6,078,839, hereinafter Carson).

Claim Rejections - 35 USC § 102

The Examiner maintains the rejection under 35 U.S.C. §102 (b) because the Helland reference does disclose and suggest that the flexibility of the membrane and the properties of the lubricious medium enable the flexible membrane to slide over the insulating housing and deform as the lead insulating housing moves relative to a patient's body tissue. Helland clearly discusses the flexibility characteristics of leads and the need for insulators to have good tensile properties and a resistance to abrasive wear. By definition, tensile implies a capability of being shaped or bent. In this connection, Helland teaches polyurethane insulation tubing having good tensile properties and the capability to be disposed over the silicone insulation tubing by first coating the outer surface of the silicone tubing with isopropyl alcohol to reduce the friction of the silicone to polyurethane, and then quickly sliding the polyurethane tubing over the silicone.

Further, the protective sleeves of Helland have great mechanical properties, such as abrasive wear resistance. It is the combination of polyurethane membrane and the silicon housing that allow for flexibility, and resistance to wear (see col. 6, ln. 55-60, Helland). The Helland reference teaches the polyurethane second insulation's ability to capitalize on its greatly lower coefficient of friction in blood and negates the higher coefficient of friction in blood of silicone (see col. 6, ln. 22-32, Helland). This suggests that relative motion between the flexible membrane and the insulating housing reduce abrasive wear of the lead body because the lead is able to slide more readily in an artery or vein or against other leads, during implantation.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 remains rejected under 35 U.S.C. 102(b) as being anticipated by Helland. The Helland reference is considered to disclose:

an implantable medical lead comprising a lead body having a proximal end carrying a connector assembly adapted to be received by an implantable medical device and a distal end, and at least one electrode connected to the lead body (see col. 3, ln. 65 – col. 4, ln. 10, Helland). The disclosed lead body is considered to anticipate the claimed lead body because both share the same shape and configuration.

an insulating housing defining an outer surface and enclosing at least one electrical conductor connecting the at least one electrode with the connector assembly

(see col. 4, ln. 10-20, Helland). The disclosed outer insulation is considered to anticipate the claimed insulating housing because both surround the conductor and form an insulation that extends from the electrode to the connector.

a flexible membrane surrounding said insulting housing having an inner surface confronting the outer surface of the housing (see col. 4, ln. 18-20, Helland). The disclosed second insulation is considered to anticipate the flexible membrane because both contact the insulating housing or the first insulation.

a lubricious medium disposed between the inner surface of the membrane and the outer surface of the housing (see col. 5, ln. 33-52, Helland). The disclosed polyurethane material is considered to anticipate the lubricious medium material because both materials facilitate movement in response to frictional engagement.

With regards to claims 2-3, Helland discloses a sealed space (see col. 7, ln. 5-15, Helland). The disclosed insulation is considered to anticipate the seal around the space between the confronting surfaces.

Referring to claims 7-10, Helland discloses a membrane with a tubular configuration disposed on the outer surface (see col. 5, ln. 58-60, Helland).

With reference to claim 11, Helland teaches a housing fabricated of silicone rubber (see col. 5, ln. 45-50, Helland).

Claim Rejections - 35 USC § 103

New claims, 22-25 are rejected under 35 U.S.C §103(a). The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4-6 and 12-15 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Helland in view of Carson.

Helland is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed lubricious medium composition of a biocompatible material. However, Carson is considered to disclose the claimed medical grade material (see col. 2, ln. 50-55, Carson). It would have been obvious to one of ordinary skill in the art to combine the teachings of Helland with the considered medical grade material teaching found in Carson for the function of the lubricious medium.

With reference to claims 22-25, Helland is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed fluid lubricious medium and fluid-tight chamber. However, Janke et al. (US 2002/0016622, hereinafter "Janke") is considered to disclose a fluid-tight chamber and lubricious medium (see paragraphs 7 and 38, Janke). It would have been obvious to

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one of ordinary skill in the art to combine the teachings of Helland with the lubricious seal and the seal provided to the ends of the lead for the purpose of injecting a lubricious medium into the membrane and sealing that medium to protect against any subsequent outside fluids or elements.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

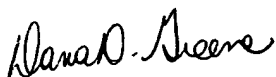
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

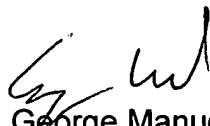
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-7138. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Dana D. Greene



George Manuel
Primary Examiner